The Zilver PTX® Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease: **5-Year Results**

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On behalf of the Investigators

Disclosure

Speaker name:

.....Hiroyoshi Yokoi.....

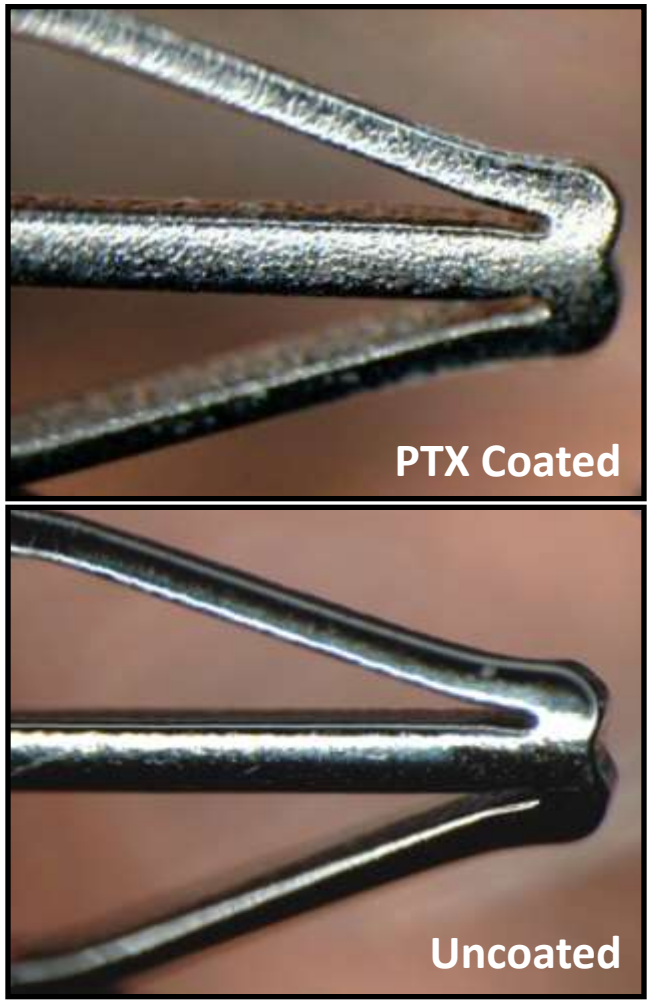
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s) Cook,

- ☐ I do not have any potential conflict of interest

Zilver PTX Drug-Eluting Stent

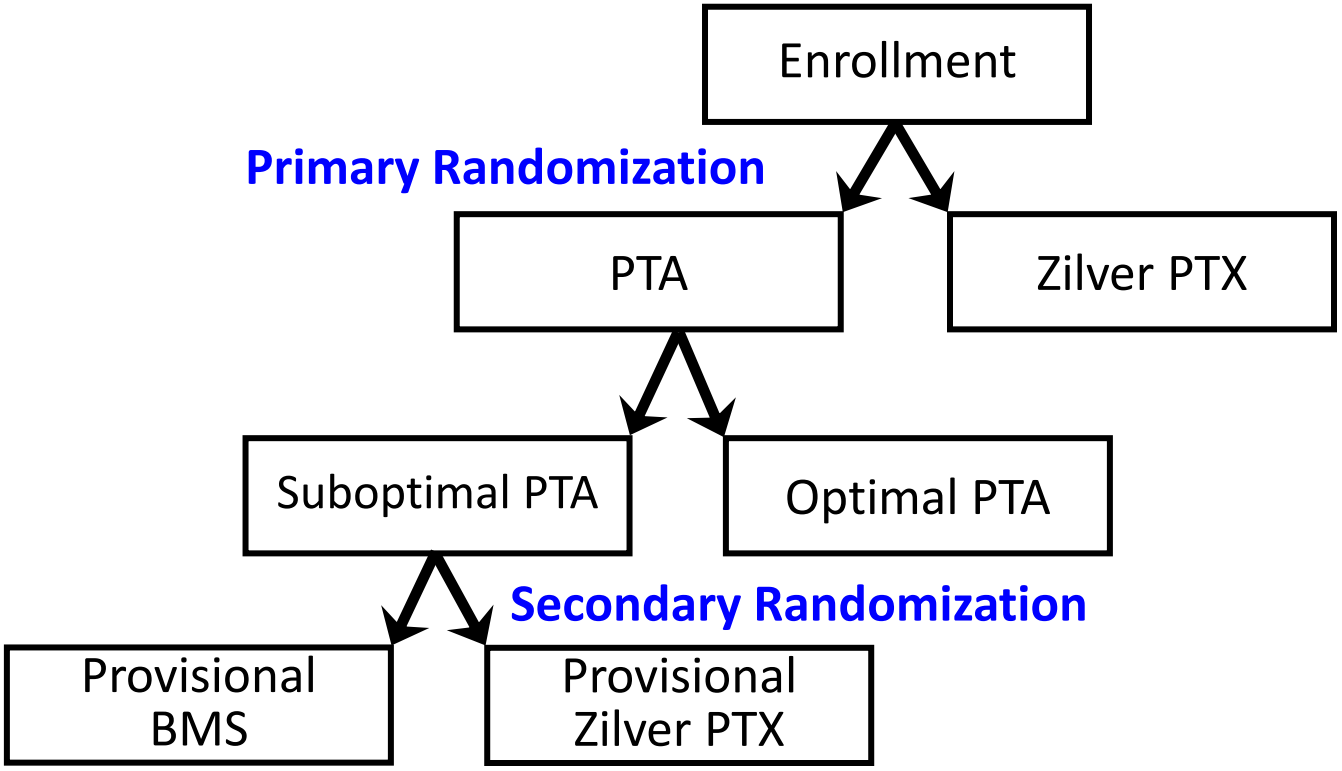
- Designed for the SFA
- Available in 50 countries including US, EU and Japan
- Dual therapy
  - **Mechanical scaffold:** Zilver Flex® stent platform
  - **Drug therapy:** Paclitaxel only
    - No polymer or binder
    - 3 µg/mm^2 dose density
- Sponsor: Cook Medical



Outline

- Study design and baseline characteristics
- Stent integrity
- Effectiveness results through 5 years
  - Zilver PTX vs. standard care
  - Provisional Zilver PTX vs. Provisional BMS
- Conclusions

Zilver PTX Study Design



Patient Demographics and Comorbidities

	PTA	Zilver PTX	*p*-value
Patients	238	236	
Age (years)	68 ± 11	68 ± 10	0.88
Male	64%	66%	0.70
Height (in)	66 ± 4	67 ± 4	0.55
Weight (lbs)	179 ± 44	180 ± 40	0.62
Diabetes	42%	50%	0.11
High cholesterol	70%	76%	0.12
Hypertension	82%	89%	0.02*
Past/current smoker	84%	86%	0.70

* Statistically significant

Baseline Lesion Characteristics

		PTA	Zilver PTX	*p*-value
Lesions		251	247	
Normal-to-normal lesion length (mm)		63 ± 41	66 ± 39	0.36
Stenosed lesion length (mm)[1,2]		53 ± 40	55 ± 41	0.71
Diameter stenosis (%)[1]		78 ± 17	80 ± 17	0.38
Total occlusions		27%	33%	0.20
***De novo* lesions**		94%	95%	0.68
Lesion calcification[1]	**None**	5%	2%	< 0.01*
	Little	38%	26%	
	Moderate	22%	35%	
	Severe	35%	37%	

[1] Angiographic core lab assessment
[2] Region with > 20% diameter stenosis
* Statistically significant

5-year Stent Integrity

Study Period	Number of New Events	Fracture Rate[1]
Enrollment	0	0.0%
1-year	4	0.9%
3-year	3	1.9%
5-year	0	1.9%

[1] Kaplan-Meier estimates

Zilver PTX has excellent durability in challenging SFA environment

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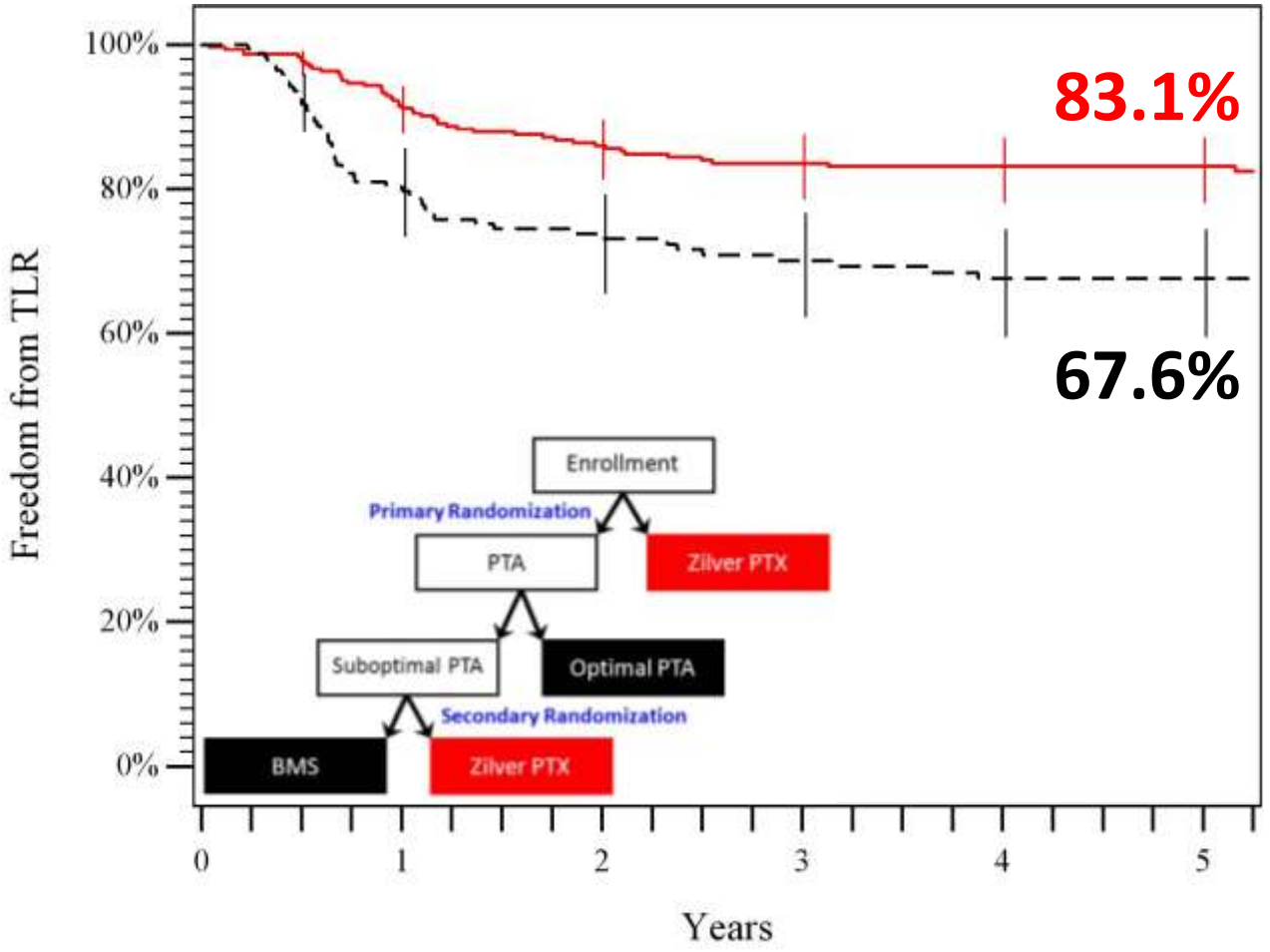
5-year Freedom from TLR
Zilver PTX vs. Standard Care

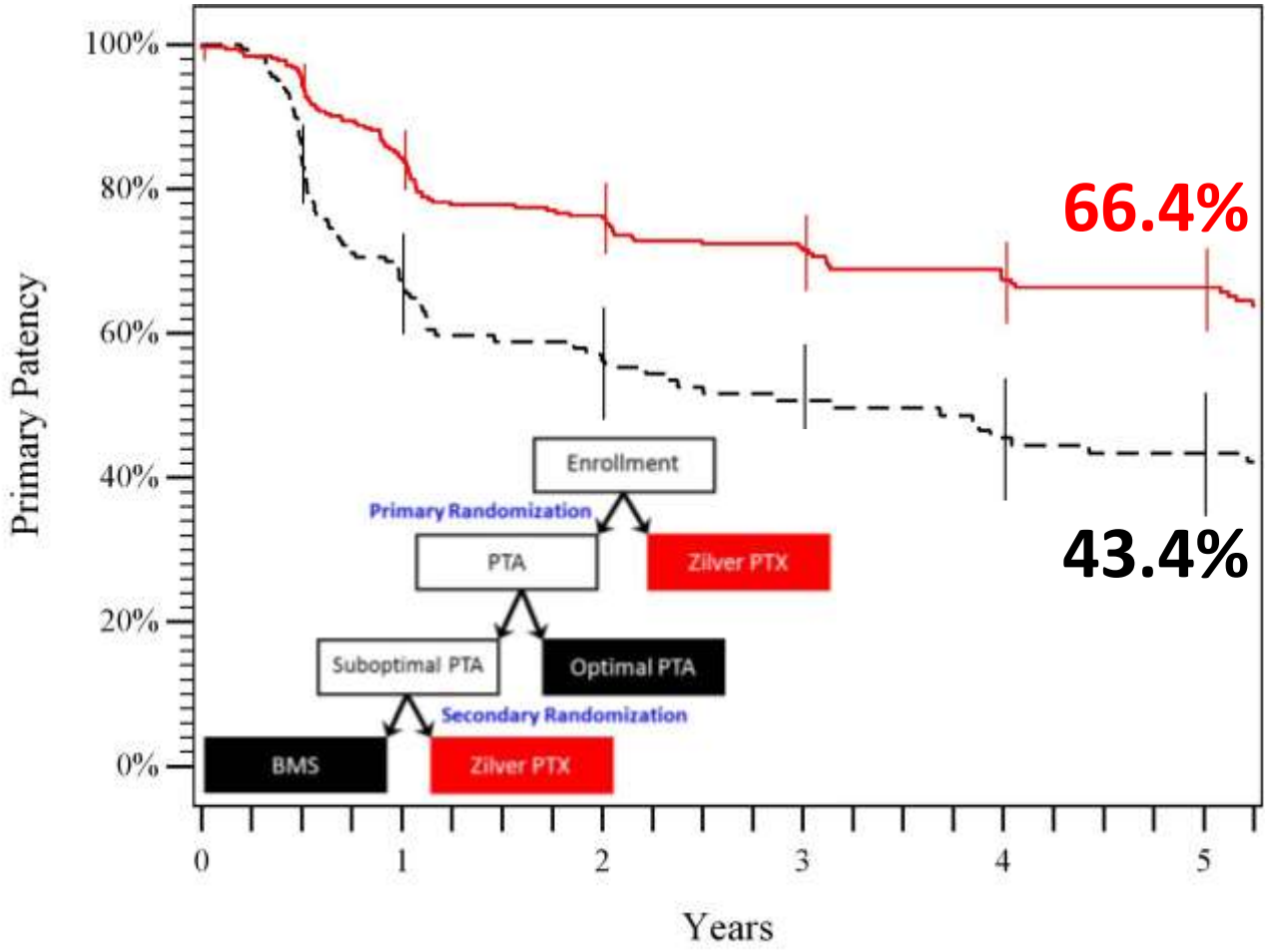


$p < 0.01$
log-rank

At 5 years, Zilver PTX demonstrates a 48% reduction in reintervention compared to standard care

5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care



66.4% Zilver PTX

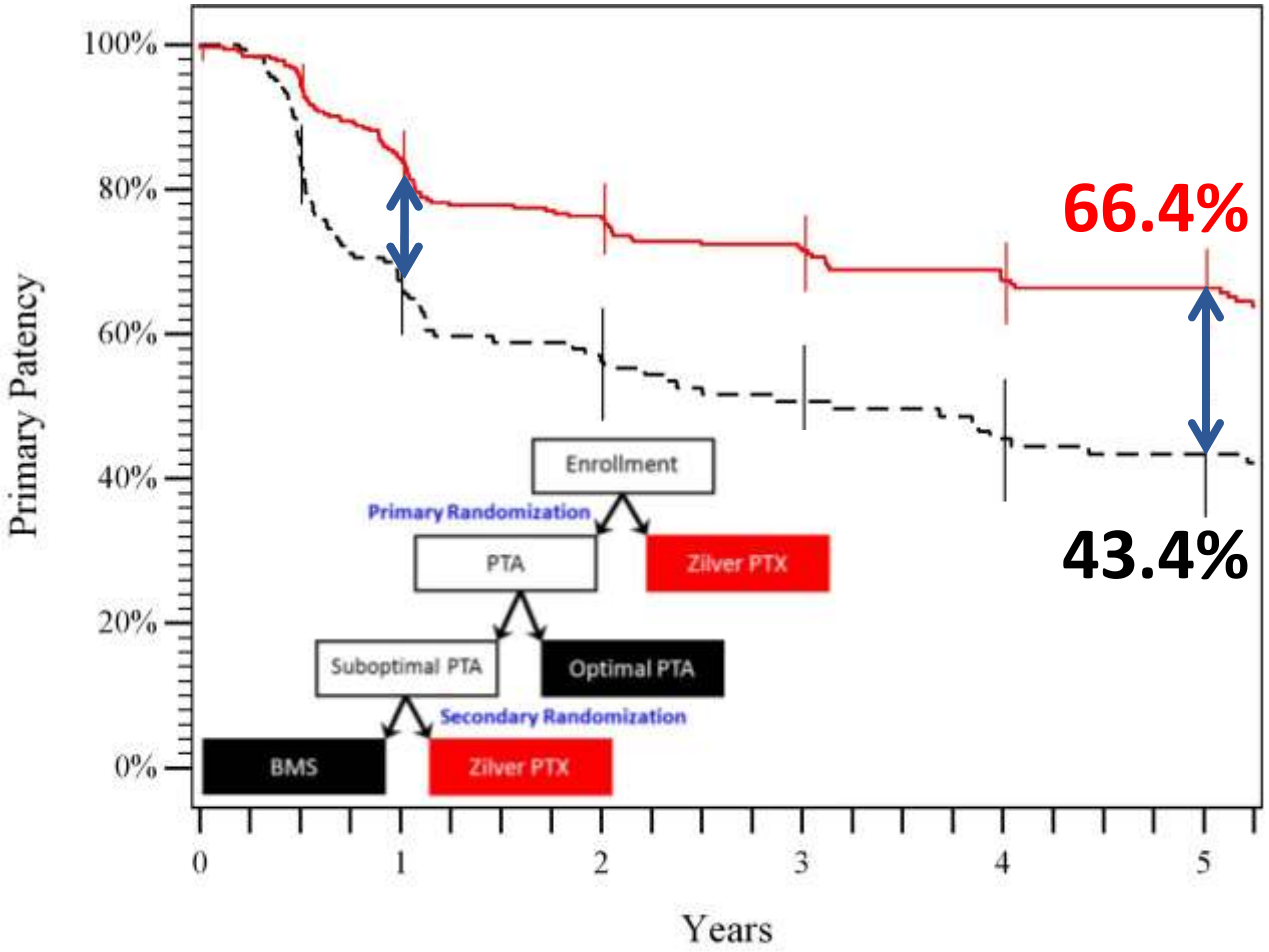
43.4% Optimal PTA + BMS

$p < 0.01$ log-rank

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care

5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care

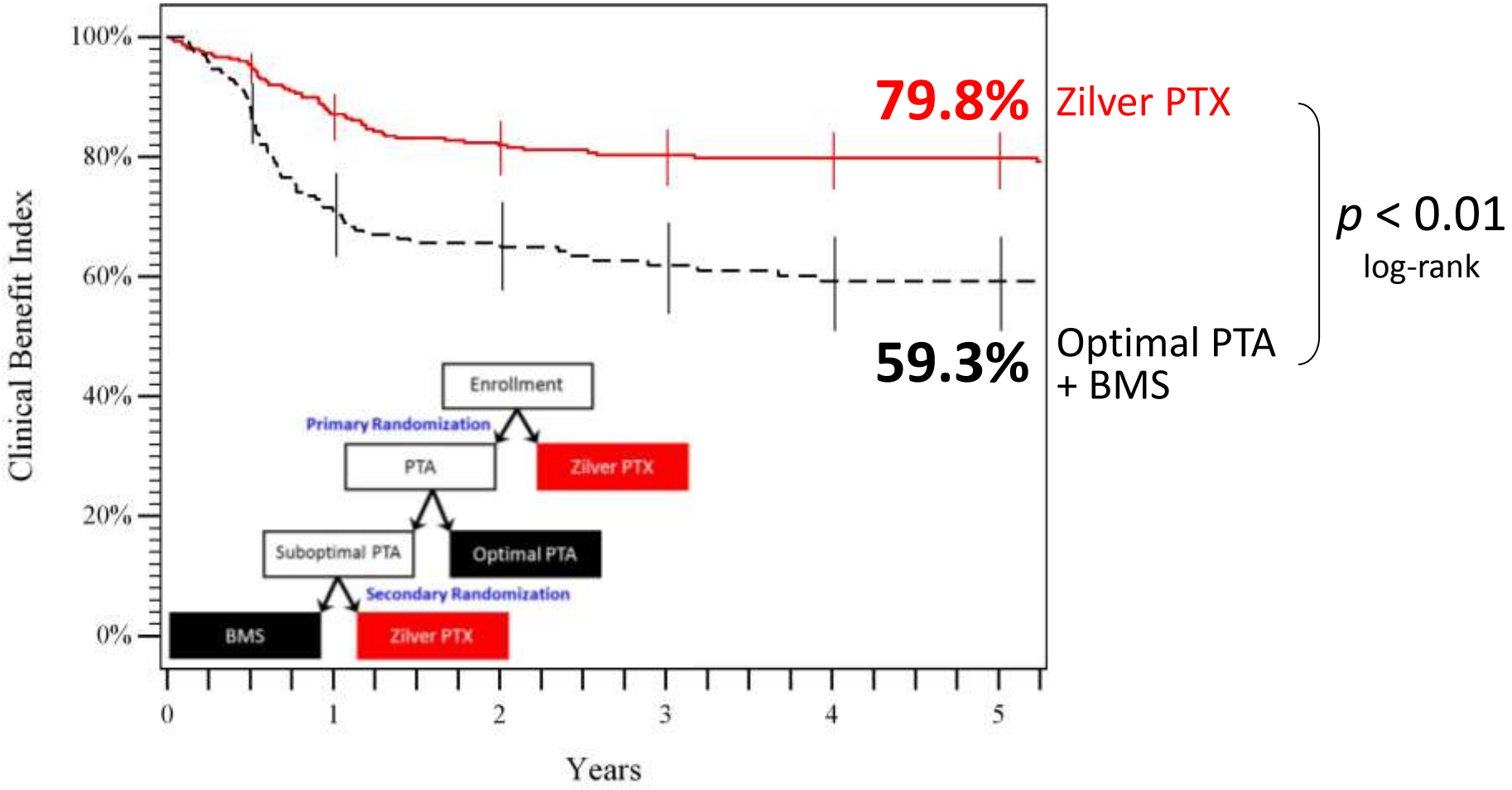


66.4% Zilver PTX

43.4% Optimal PTA + BMS

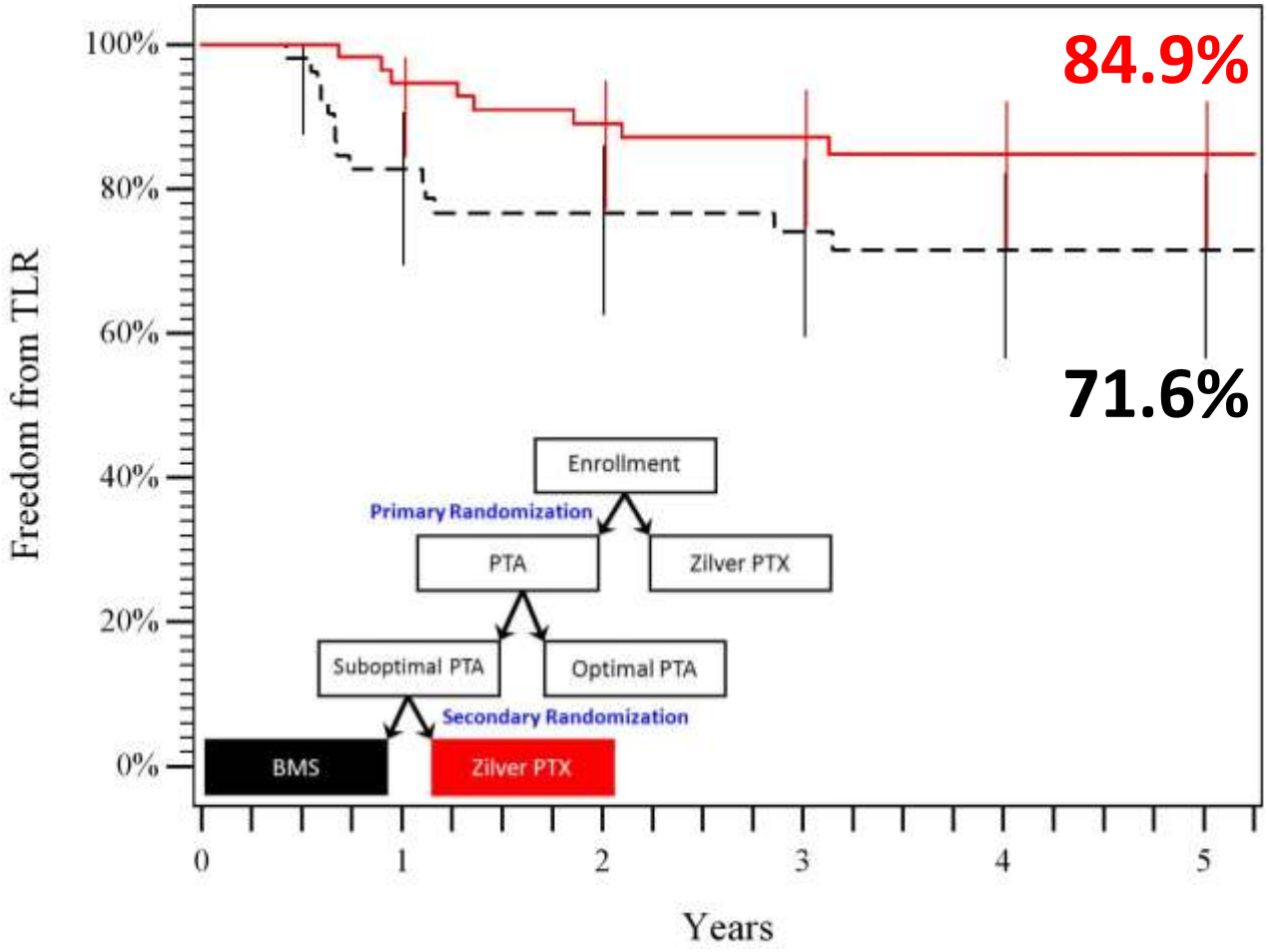
From 1-5 years, the relative separation increases by 35%

5-year Clinical Benefit Index
Zilver PTX vs. Standard Care



At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss

5-year Freedom from TLR
Provisional Zilver PTX vs. BMS

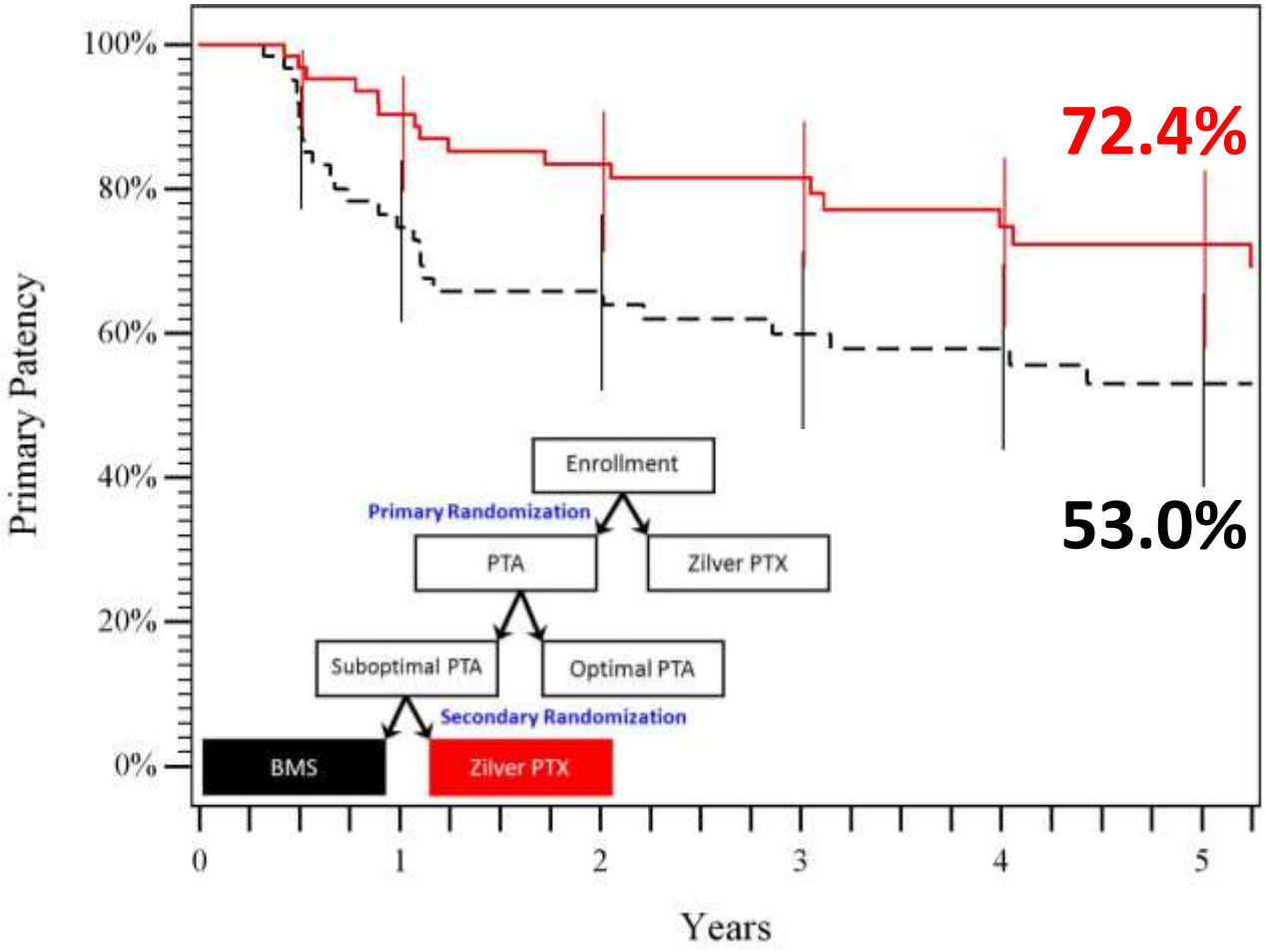


$p = 0.06$
log-rank

At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS

5-year Primary Patency (PSVR < 2.0)

Provisional Zilver PTX vs. BMS



72.4% Provisional Zilver PTX

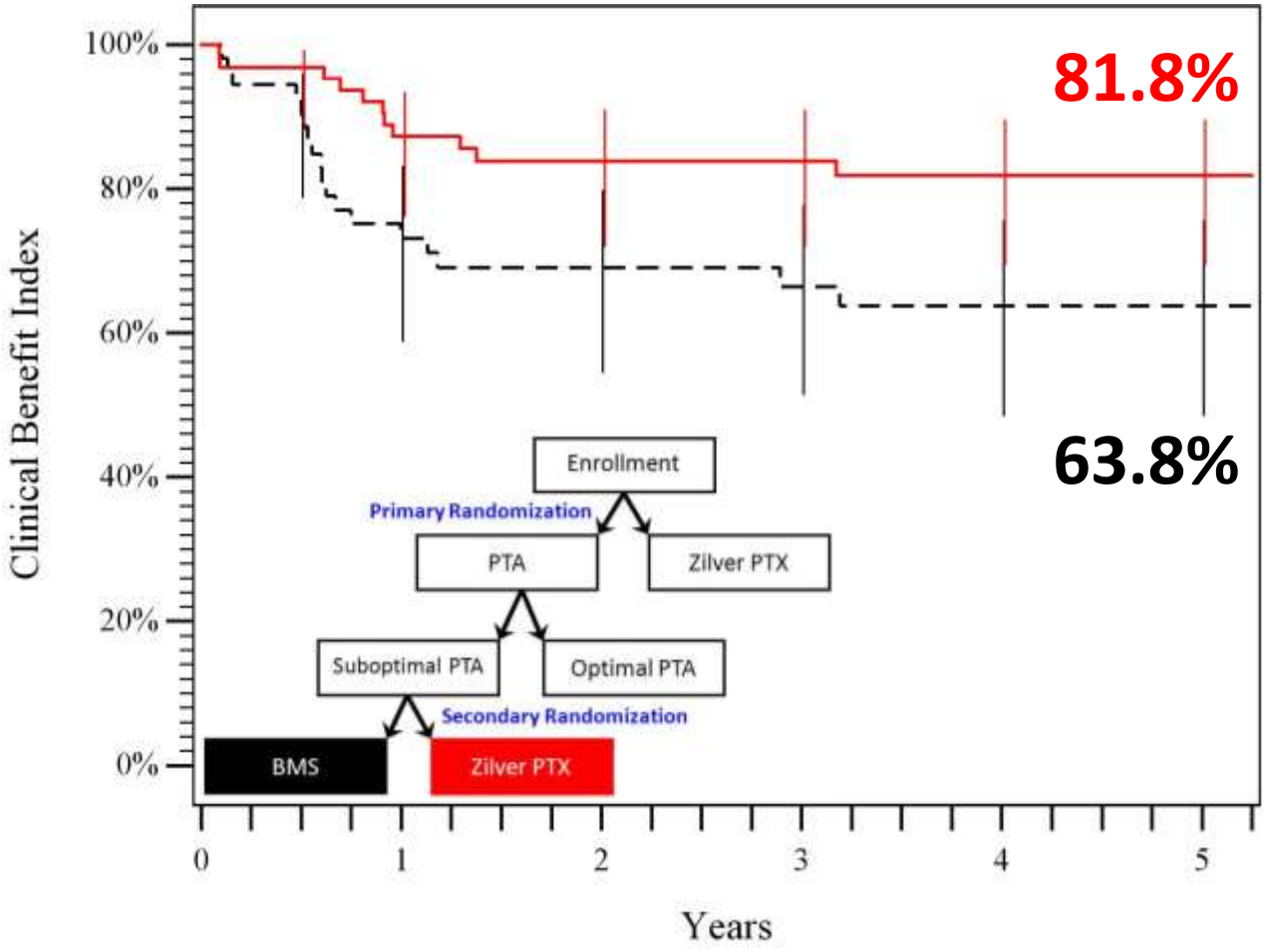
53.0% Provisional BMS

$p = 0.03$
log-rank

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS

5-year Clinical Benefit Index

Provisional Zilver PTX vs. BMS



$p = 0.02$
log-rank

At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss

Conclusions for 5-year Zilver PTX RCT

- As the first randomized controlled SFA device trial with 5-year follow-up, these results with the Zilver PTX stent provide important insights regarding long-term outcomes for endovascular treatment
- 5-year data for Zilver PTX versus standard care
  - Greater than 40% reduction in reintervention and restenosis
  - Superior clinical benefit
  - These benefits increase with time – results with Zilver PTX continue to diverge from standard care over 5 years with no late catch-up
- 5-year results confirm long-term superiority of Zilver PTX versus bare metal stents

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